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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,678	03/11/2004	Max F. Rothschild	P04474US02	6258

22885 7590 11/01/2005

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EXAMINER	
SWITZER, JULIET CAROLINE	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,678	ROTHSCHILD ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *13-22 and 26-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-5,30-32 and 43-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 23, 24, 25, 30-36, 43-44, and 45-51, drawn to methods for genetically identifying animals as they relate to assaying for the presence of a polymorphism within the CKM gene, classified in class 435, subclass 6.

II. Claims 1-5, 13-19, 26-28, 30-32, 37-40, 43-48, drawn to methods for genetically identifying animals as they relate to assaying for the presence of a polymorphism within the SCN4α gene, classified in class 435, subclass 6.

III. Claims 1-5, 20, 29, 30-32, 41-48, drawn to methods for genetically identifying animals as they relate to assaying for the presence of a polymorphism within the LDHα gene, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not related insofar as they each relate to the association of distinct polymorphisms with meat quality and growth traits in animals. The relationship of polymorphisms in one gene with a phenotypic trait is likely not predictive of the relationship of polymorphisms in another gene, and a reference for one would not necessarily be a reference against another.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-III require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Heidi Nebel on 5/26/05 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-12, 23, 24, 25, 30-36, 43-44, and 45-51, as they relate to the CKM gene. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-22, 26-29, and 27-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. The information disclosure statement filed 11/3/04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the citation does not provide a full citation of the reference including page numbers of the article. The article has been considered. If applicant desires for the reference to appear on the front of any eventually issued US Patent, the citation should be corrected on a new 1449.

Claim Objections

7. Claims 1, 2, 3, 4, 5, 30, 31, 32, 43, 44, 45, 46, 47, and 48 are objected to for reciting non-elected subject matter. These claims all recite the detection of polymorphisms in the SCN4α or LDHα genes. Removal of the non-elected subject matter is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-12, 23-25, 30-36, and 43-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 23, 24, and 24 are indefinite over the recitation "favorable muscle growth and/or meat quality" in claim 1. It is not clear if the "favorable" is meant to modify only muscle growth or both muscle growth and meat quality. Further, the claims are indefinite because the whether or not a particular trait is favorable is entirely context dependent, and is subjective in nature, it is unclear what the recited polymorphisms are associated with. First, the claim does not set forth what the standard of comparison is for the favorability. That is, the animals identified by the screen will have favorable meat quality traits compared to which other animals. Also, it is unclear what standard for favorability in muscle growth or meat quality traits is being applied in the instant methods, as one person's idea of an "favorable" meat quality trait may be different from another person's idea of an improved meat quality trait. For example, the instant specification teaches that for at least some measures of meat quality, the desired score on a test is different for Japanese populations versus other

populations. Thus, simply to recite a method for screening for "favorable muscle growth and/or meat quality traits" is indefinite because it is unclear in whose view the favorability is to be judged, and thus, it is not clear what would constitute an improved meat quality. Claims 30, 32, 32, 33, 34, 35, 36, 43, and 44 are likewise indefinite over the recitation of "favorable breeding traits" because like with meat quality, a trait which is "favorable" is context dependent. Claims 45 and 46 are likewise indefinite over the recitation of "favorable combination of traits for muscle growth and/or meat quality" and claims 49-51 are indefinite over the recitation "favorable meat quality" for analogous reasons.

Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 23, 24, and 24 are indefinite over the recitation "assaying for the presence of a polymorphism" because it is unclear from the claim how to identify "the presence of a polymorphism." A polymorphism is a difference in a nucleotide sequence among individuals, and if one is looking at the genetic material from "an animal" it is unclear how one would identify a polymorphism within the individual. Generally, within one individual, one identifies the genotype of the individual at a particular polymorphic site, wherein one particular allele of the genotype might be associated with different versions of a particular trait. For example, the first allele might be associated with increased pH while the second allele might be associated with decreased pH. Clarification of what is actually being detected is required. Claims 30, 32, 32, 33, 34, 35, 36, 43, 44, 47, 48, 49, 50, and 51 are likewise indefinite over the recitation of the "presence of a polymorphism" language. In these claims amendment of this language to better reflect that it is the presence of a particular allele at a polymorphic site which is correlated with the trait may overcome the rejection.

In claims 31 and 32, it is not clear how the language "or an insertion or deletion" is related to the other method steps in recited in claim 31. Is the insertion or deletion being detected by the previously recited "generating or destroying a restriction site in a sample?"

Claims 45 and 46 are indefinite because it is not clear how the method steps in the claims accomplish the goal of the claims as set forth in the preamble of claim 45. The preamble of the claim recites a method for genotyping "to determine whether it possesses a favorable combination of traits for muscle growth and/or meat quality" but eh single method step of the claims recites determining the alleles present in an animal at particular polymorphic sites. There is no recitation in the claim that makes a connection between the presence or absence of the restriction sites and a favorable combination of traits.

Claims 47 and 48 are indefinite over the recitation of sequence identifiers in parenthesis within the claim, because it is not clear if these are intended to set forth positive limitations, for example in part (a) so as to require that the polymorphism is detected within SEQ ID NO: 2, or if they are meant to give possible examples of the recited region.

Claims 49, 50 and 51 are indefinite because it is not clear gene the recited polymorphisms are within, since the claim recites a MspA1I and a 9 bp insertion/deletion but does not provide any context for these polymorphisms.

Claim 50 is indefinite because it is unclear what the arbitrary identifiers "1-1, 1-2, and 2-2" mean in the context of the claim.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-12, 23, 24, 25, 30-36, 43-44, and 45-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Nature of the Invention and Breadth of the claims

Claims 1-12, 23, 24, and 25 are drawn to methods for genetically identifying an animal comprising assaying for the presence of a polymorphism in the CKM gene, wherein the presence of the polymorphism is associated with "favorable muscle growth and/or meat quality." Claims 45-46 recite a method for genotyping an animal to determine whether it possesses a favorable combination of traits for muscle growth and/or meat quality via genotyping at particular polymorphic sites within CKM. Thus, the nature of the invention requires the knowledge of a predictive relationship between polymorphisms in the CKM gene and favorable muscle growth and/or meat quality.

Claims 30-36 and 43-44 are similar to the previous claims, except that they are methods for screening an animal to determine said animal's genetic potential for animal breeding and include a step of making genetic assessments based upon the presence of a polymorphism in said gene which is correlated with favorable breeding traits. Thus, for these claims, the nature of the invention requires the knowledge of a predictive relationship between polymorphisms in the CKM gene and favorable breeding traits.

Claims 47 and 48 simply recite a method for genotyping an animal at a polymorphic locus. The claims do not recite a purpose for the claimed method, but in order to use the claimed method, the knowledge of an association between one of the three recited polymorphisms in the CKM gene and some phenotypic trait would be required.

Claims 49 and 50 recite a method for detecting the presence of haplotypes which are predictive for determining the presence of a gene linked with favorable meat quality in an animal via analyzing genetic material for polymorphisms.

The nature of the invention is that it relies on analysis of biological samples for the detection of particular alleles at present at polymorphic sites. Based on the presence or absence of particular alleles, one can presumably make assumptions about the likelihood of the "favorable muscle growth and/or meat quality." The invention sets forth a screen for animals possessing "favorable" meat quality traits, but does not set forth in whose eyes the favorability is to be measured. Meat quality is largely a matter of relative opinion, with some individuals preferring meat with particular traits and others preferring different traits. Thus, the judgment of an "favorable" meat quality is largely subjective. The instant specification teaches that the whether the lightness of meat is favorable is dependent upon the market (p. 6, line 20).

The invention encompasses the prediction of meat quality traits in any animal for which this might be of interest, and since a wide variety of animals are raised for meat production (including, for example, pigs, sheep, cows, buffalo, chickens, turkeys, geese, game hens, frogs, fish of all kinds, sharks), the scope of these claims is quite broad with respect to animal type encompassed.

Furthermore, the invention encompasses the prediction of meat quality based any possible meat trait. Encompassed within the prediction of "favorable muscle growth and/or meat quality" is the prediction of heavy muscling, and/or the likelihood of skeletal muscle cramping disease (specification p. 19, line 17). The specification teaches that it means "a significant increase or decrease (improvement) in one of many measurable meat quality or muscle growth traits above the mean of a given population.

Many of the claims are also inclusive of the detection of any possible polymorphism within the CKM gene, which encompasses an undefined number of nucleotides up and down stream of the actual coding region of the gene, as well as all introns, and as mentioned the claims include the assay of these undefined polymorphisms in any species of animal.

Teaching in Specification

The examples in the specification address only the porcine CKM gene, and further teaches examples that are specific to only three particular portions of the porcine CKM gene.

The specification teaches the sequencing of the full cDNA and part of the 5' and 3' UTR of porcine creatine kinase muscle gene (CKM) (Example 1, p. 34), and gives assays for the detection of three polymorphisms within the gene. The specification gives partial sequences of the porcine CKM gene (instant SEQ ID NO: 1 and SEQ ID NO: 2). The specification does not give the entire coding sequence of the gene, nor does it give the entire genomic sequence or the sequence of the 3' untranslated region of the gene.

The three polymorphisms disclosed in the specification include, first a C→T polymorphism within the 5' UTR that can be identified with the restriction enzyme MspA1I in a region of the gene amplified by SEQ ID NO: 7 and SEQ ID NO: 8 (p. 36). Second, a G→T

polymorphism which is in an intron and can be identified with the restriction enzyme Bam HI in a region of the gene amplified by SEQ ID NO: 9 and SEQ ID NO: 10 (p. 37), and third, a 9 base pair insertion deletion polymorphism identifiable using PCR with SEQ ID NO: 11 and SEQ ID NO: 12 and then gel electrophoresis to determine amplicon size (p. 39).

The specification teaches the testing for associations between a number of different meat traits in several commercial populations. The results are given in a number of different tables throughout the specification. For the at least twelve different meat quality traits tested in the specification, there were very few statistically significant results found, and there was no result that was significant at the $p<0.05$ level for more than two different test populations. The specification does not teach that any single marker with in CKM is reliably associated with any particular meat quality trait in the different pigs tested, nor does the specification even attempt to demonstrate that polymorphisms within CKM are associated with any measures of meat quality or muscle growth in any animal other than pigs. As Thisted et al. notes, "It has become scientific convention to say that p-values exceeding 0.05 (one in twenty) just aren't strong enough to be the sole evidence that two treatments being studied really differ in their effect (see page 5)."

Table 3, on page 48, provide "Association analysis results (probabilities) between CKM MspA1I alleles and meat quality traits in several commercial line populations." For each trait represented in the table, a significant result was observed in a different population. No two populations had a significant association between a trait and allele frequencies for the same trait. For example, the Berkshire population had a significant result for firmness and drip prct, but did not have significant results for the other tested traits. Likewise, Duroc 1 had significant results for loin min1, loin minb, DG (daily gain), and muscle depth, but not for other traits. The

population labeled Duroc 2 did not have any significant results for any of the traits tested. In this example, no guidance is given as to which allele for any of the traits is associated with "favorable muscle growth and/or meat quality," even in the cases where the results suggest a possible association.

On page 49 another table is given showing results of testing for relationships between the **MspA1I** polymorphism and traits in a population referred to as "Genotype Linecross A" which had 548 members. Significant results were observed for the traits pH24 hr, Minolta L, Minolta b, and Drip % but not for pH 45min, pH 3 hr, or Minolta a. In a second population, "Genotype Linecross B," no significant effects were observed for any traits where the 22 genotype was absent. On page 50, the specification teaches that results with $p<0.05$ were observed for pH24 hr, Minolta L, Minolta b, and drip % but not for pH 45min, pH 3 hr, or Minolta a when associations were tested between these traits and the **BamH1** genotypes in the Genotype Linecross A population in a sample of 601 pigs (p. 50). Thus the results for the two single nucleotide polymorphisms were very similar in the Linecross A population.

For the Linecross Genotype A population, effects significant at $p<0.05$ were observed for the **9 bp deletion** for the traits ham %, pH 3hr, pH24 hr, and Minolta b, but not for carc. wt., loin %, lea, loin depth, lean %, pH 45 min, Minolta L, Minolta a, and drip % (p. 50-51). For pH24 hours and Minolta b, the results were the same as for the SNP, but not for the other traits. Also unlike the SNP, significant effects were observed at $p<0.05$ for the traits lea and loin depth, but not for some other listed traits. The specification summarizes that "higher yields are associated with allele 2 in Linecross Genotype A and with allele 1 in Linecross Genotype B...allele 2 is also associated with lower meat quality as judged by higher pH of 24, lighter meat,

and higher drip loss (p. 51, lines 6-9)." Thus, regarding meat yield, the results conflict with regard to which allele is predictive in which population.

Regarding muscle growth, does not provide any data which demonstrates a reliable association between any of the three polymorphisms and favorable muscle growth in pigs, let alone any other animal, and further does not provide any data regarding heavy muscling or skeletal muscle disease.

Overall, these results indicate that it is highly unpredictable which associations could be relied upon for the testing of any trait in any or all pig line populations since there does not appear to be any consistent result, and in some cases the same allele was predictive in opposite ways in different groups of subjects.

State of the Art, Level of skill in the Art, and Level of Unpredictability in the Art

The prior art does not provide the nucleotide or amino acid sequences for the CKM gene of other meat species of animals, nor does the prior art provide the full length sequence of the porcine CKM gene. The prior art does not provide any additional polymorphisms within the porcine CKM gene that are associated with meat quality traits.

The specification demonstrates the high level of unpredictability of this invention, since for many of the traits tested in particular test groups, no reliable association was able to be identified for all three of the polymorphisms tested, or an association was detected for one of the polymorphisms but not for any of the others. In addition, in the Duroc 2 population, no association was observed between any traits and any alleles of CKM. Thus for observations where $p>0.05$ it is highly unpredictable as to whether the tested polymorphism is in fact associated with any of the traits. Looking at the Linecross A population, the trait "Minolta A"

was not significantly associated with allele frequencies for any of the three polymorphisms. The trait "pH24" was significantly associated with all three alleles at $p<0.05$. The trait "Minolta L" had a significant association with only two of the three disclosed polymorphisms.

The level of skill in the pertinent art is quite high, i.e. generally a PhD in biochemistry, but the unpredictability in the art is higher. While the instant specification has disclosed a three of different polymorphisms in the porcine CKM gene, it remains highly unpredictable that any of these polymorphisms exist in other species of animals, and even if they do exist, that they are indicative of any particular phenotypic trait. Vincek *et al.* (Mammalian Genome 5, 376-379 (1994)) demonstrate that polymorphisms that are present in the beta globin region in human were not able to be located in chimpanzee and gorilla. Thus, simply because a particular polymorphism is present in one species of animal, there is no evidence that it will be present in another animal.

The ability to apply the assays disclosed in the instant specification to a wide range of animals relies on an assumption of a structure/function correlation across different species of animals, however, no evidence of such a relationship has been provided in the specification. The application of the instantly disclosed assay to additional species of animals requires one to assume that these particular polymorphisms will be present at "equivalent positions" in other animals, however, applicant has not disclosed the importance of these polymorphisms for the function of the CKM gene or encoded polypeptide, and so it is difficult if not impossible to determine the equivalent positions in the undisclosed CKM genes of other animals. Applicant has not provided any guidance as to how to determine which nucleotide acid position in the other species of animals would be the "equivalent" positions of the polymorphisms in the porcine

CKM. No guidance is provided in the specification to further guide the practitioner to the "equivalent" positions, and such a determination is highly unpredictable.

The prior art does not provide the sequence of the CKM gene in other meat producing animal species, and neither does the instant specification. Due to this lack of critical information about the sequence of the CKM gene in other animal species, at the time the invention was made it was not possible to even predict what the equivalent positions of the polymorphisms disclosed herein would be in other animals. Further, it is not even clear that the CKM gene in other species of meat producing animals would have the same effects on meat quality as the CKM gene in pigs. Juppner (Bone Vol. 17, No. 2, Supplement, August 1995: 39S-42S) teaches that despite significant structural conservation, rat, opossum, and human PTH/PTHrP receptor homologs display distinct functional characteristics (ABSTRACT and p. 39S-40S). Thus, even if homologues of CKM gene were identified and sequenced in other animals, and even if these displayed polymorphisms, it is highly unpredictable as to whether these putative polymorphisms would be indicative of any particular meat traits in the animals.

Quantity of Experimentation

An extensive, and prohibitive amount of experimentation would be required to practice this invention commensurate with the full scope of these claims. Applicants have screened for many different factors of meat quality in at least seven different populations of pigs and were unable to provide any consistent guidance with regard to precisely which polymorphism would be indicative of which trait in pigs. Because there is no reason to expect that the instantly disclosed polymorphisms would exist in species of animals other than pigs, or that other polymorphisms exist within the CKM gene that are indicative of meat quality traits, screening

for additional polymorphisms in pigs or other animal species would require breeding and screening hundreds of thousands of animals. There is no evidence, however, of any frequency of significant polymorphisms in other meat producing animals, a genus which encompasses fowl, mammals, and indeed, even some reptiles. Further, as noted above, even in positive matches, and in pigs the CKM polymorphism may not correlate with meat quality traits, since such a correlation is highly unpredictable.

Conclusion

Thus, having carefully considered all of these factors, it is concluded that it would require undue experimentation to practice the claimed invention.

12. Claims 1, 2, 3, 4, 5, 6, 7, 9, 11, 23, 24, 25, 30, 31, 32, 33, 43, 44, 47, 48, 49, 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass the detection of a genus of nucleic acids which comprise CKM polymorphisms which are not disclosed in the specification, and for claims 49-51 which comprise polymorphisms in any gene, since no gene is recited in the claim. The genus includes an enormous number of polymorphisms for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named three polymorphisms within the porcine CKM gene. Thus, applicant has express possession of only three particular polymorphisms, in a genus which comprises hundreds of millions of different possibilities. Further, the specification provides only two fragments of the porcine CKM gene, and neither the specification nor the prior art provide a complete sequence of the porcine CKM gene or any other meat producing animal's CKM gene. Here, no common element or attributes of the sequences are disclosed which would permit selection of sequences as polymorphisms. Even in the narrower dependent claims, such as claim 7, where MspA1I is required, no specific polymorphism is named. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations of associating a polymorphism with litter size is provided. Further, these claims expressly encompass all the different possible allelic variants including insertions, deletion, substitutions and transversions at thousands of different sites. No written description of alleles, of upstream or downstream regions containing additional sequence, which are associated with any phenotype are described in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition in claim 1 of a polymorphism associated with favorable meat growth and/or meat quality which lacks any specific structure, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the three specific polymorphisms, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to a method for using a polymorphism in the CKM receptor gene, for example.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely but its functional utility, as a polymorphism, without any definition of the particular polymorphisms claimed.

In the instant application, certain specific polymorphisms are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise CKM gene polymorphisms. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 47 is rejected under 35 U.S.C. 102(b) as being anticipated by Benfield et al. (Gene, 63, (1998) 227-243).

Benfield et al. teach a method comprising the steps of obtaining a genetic sample from an animal and assaying for the presence of a polymorphism located in the CKM gene in the 5' untranslated region of said gene (p. 229 and figure 7). Namely, Benfield et al. sequence the 5' untranslated region of the rat CKM gene, such a method inherently detects the nucleotide present at each position of the sequence, and thus detects the presence of the allele present at each polymorphic site within the sequence.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday or Thursday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

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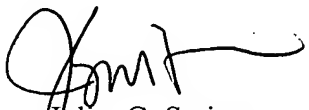

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Art Unit 1634

October 27, 2005